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Via Federal Express

TSCA Confidential Business Information Center (7407M)

EPA East - Room 6428 Attn: Section 8(e)

U.S. Environmental Protection Agency

1201 Constitution Avenue, NW

Washington, DC 20004-3302

Subject: Notice in Accordance with TSCA Section 8(e): Results of an OECD 421
Reproduction/Developmental Toxicity Screening Test in Wistar Rats, administration via
gavage, with Aminoguanidinium hydrogen carbonate, CASRN 2582-30-1

Dear Section 8(e) Coordinator:

BASF Corporation is submitting interim results of an Reproduction/Developmental Toxicity Screening Test in Wistar Rats [CrI:WI(HAN) Charles River, Sulzfeld, Germany], administration via gavage, with Aminoguanidinium hydrogen carbonate (CASRN 2582-30-1), conducted by BASF SE, Ludwigshafen, Germany.

The study was carried out in accordance with the requirements of international guidelines such as:

- OECD Guidelines for Testing of Chemicals, Guideline 421
- EPA, Health Effects Test Guidelines; OPPTS 870.3550

The test substance was administered to groups of 10 male and 10 female young Wistar rats (F0 parental generation) as suspension in 1% Carboxymethylcellulose in drinking water, via daily gavage. The dose levels were 0, 100, 300 and 1000 mg/kg body weight/day. About 2 weeks after the beginning of treatment, F0 animals were mated to produce a litter (F1). Mating pairs were from the same dose group. Pregnant females were allowed to give birth and the offspring was brought up until postnatal day (PND) 4. The study is terminated with the sacrifice of the F1 pups on PND 4 and of lactating dams shortly thereafter.

The following is a summary of the most relevant interim results:

1000 mg/kg bw/d:

- Salivation in males during premating and mating (up to 4 of 10 animals) and in females during gestation (1 of 10 animals)
- Piloerection and high stepping gait in females during gestation (1 of 10 animals) and lactation (up to 4 of 10 animals)
- Reduced food consumption in males (-19%) and females (-17%) in the first week of premating and in females during lactation (-24%)
- Slight reduced body weight in males during premating and mating (-6%) and in females during lactation (-8%)
- Two animals with complete litter loss
- 20 Pups (28%) are found dead/stillborn/cannibalized



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- Reduced pup weights in males (-9% day 1) and females (-10% day 1)
- 38 Pups (53%) with various alterations of the pericardial blood vessels (aneurysm in ductus arteriosus, pulmonary artery resp. aorta)

300 mg/kg bw/d

- Salivation in females during gestation and lactation (1 of 10 animals)
- 1 Pup (2%) are stillborn
- 4 Pups (7%) with various alterations of the pericardial blood vessels (aneurysm in ductus arteriosus, pulmonary artery resp. aorta)

100 mg/kg bw/d:

- 2 Pups (2%) are found dead/stillborn
- 2 Pups (2%) with various alterations of the pericardial blood vessels (aneurysm in ductus arteriosus resp. aorta)

In the time frame between lactation and necropsy of the female animals of the 1000 mg/kg body weight/day group the following clinical findings are observed:

- One female animal was sacrificed in a moribund state (poor general condition/paresis/hypothermia/urine stained anogenital region)
- All animals showed gait abnormalities as high stepping and or unsteady gait. In 8 (out of 10) animals paresis of the hind limbs were seen shortly before the scheduled necropsy

The data evaluation of the study is ongoing.

BASF Corporation understands that reporting of the results from this study under TSCA 8(e) is in accordance with EPA's policy.

Please note the technical contact and address below and direct all correspondence regarding this submission accordingly. If you have any questions, please call (248) 948-2051.

Sincerely,

Technical Contact: Alisa Boucher

BASF Corporation
Product Regulatory Center of Expertise – North America
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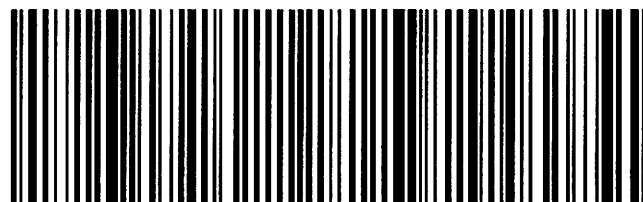
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